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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,878	01/25/2001	John E. Sims	2976-B	7821

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EXAMINER

HAMUD, FOZIA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

12

Office Action Summary	Application No. 09/769,878	Applicant(s) SIMS, JOHN E.	
	Examiner Fozia M Hamud	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,11,15,17 and 32-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,11,15,17 and 32-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Office Action

1a. Receipt of Applicants' amendment and arguments filed on 05 September 2003 is acknowledged. Claims 8-9 and 18-31 have been canceled, and claims 32-37 have been amended.

Status of claims:

1b. Claims 2-7, 10 and 12-14, 16 have been canceled in the amendment filed on 04 March 2003 and claims 8-9, 18-31 have been cancelled in the amendment filed on 05 September 2003. Claims 1, 11, 15, 17 and 32-38 are pending and under consideration.

2. The following previous objections and rejections are withdrawn in light of Applicants amendment filed on 09/05/03:

(I) The rejection of claims 32-38 made under 35 U.S.C. 112, second paragraph.

Claim Rejections under 35 U.S.C. §101/112:

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3a. Claims 1, 11, 15, 17 and 32-38 stand rejected under 35 U.S.C. §101 for reasons of record set forth in the action mailed on 21 August 2002 in Paper NO:7, pages 6-9 and reiterated in the office action mailed on 03 June 2003, pages 3-7.

Applicants argue that in order to fulfill the requirement under 35 U.S.C. §101, it is only required that Applicants' nucleic acid be useful to some extent and certain applications. Therefore, Applicants argue that their nucleic acids does not have to be the best or the only way to identify human chromosome 2 or to analyze abnormalities associated with genes mapping to chromosome 2. Applicants submit that their nucleic

Art Unit: 1647

acid can be used to distinguish conditions in which this marker is rearranged or deleted, or to serve as a positional marker to map genes of unknown location. Applicants submit that the claimed nucleic acid (or fragments thereof), can be used by the skilled artisan, using well-known techniques to analyze abnormalities associated with genes mapping to chromosome 2. Applicants argue that the mere fact that the claimed nucleic acid can be used in a research setting to detect abnormalities or the presence of specific polymorphism is not dispositive of a lack of "real world" utility. Finally, Applicants contend that since the claimed nucleic acid is located to the proximal region of chromosome 2, it is useful as a probe for detecting the abnormalities associated there.

Applicants' arguments have been fully considered, but are not deemed persuasive. Firstly, the Examiner agrees with Applicants that in order to fulfill the requirement under 35 U.S.C. §101, all that is required is for Applicants' nucleic acid to be useful to some extent and certain applications. However, in the instant case, Applicants have failed to provide a single specific use or substantial utility for the claimed nucleic acid. Applicants have not shown whether the claimed nucleic acid is associated with only normal conditions or whether it is associated with abnormal conditions, mapping to chromosome 2. Applicants have not disclosed conditions in which the claimed nucleic acid is either deleted or rearranged. Instant specification only discloses that claimed nucleic acid maps on human chromosome 2, 2q11-12, however, Applicants have not disclosed whether said nucleic acid is involved any disorder that maps on this chromosome.

Applicants cite Exhibits 1-6, as support that their nucleic acid is useful as a probe for detecting abnormalities on chromosome 2. However, all of the references submitted by Applicants (Exhibits 1-6), disclose specific genotype-phenotype correlation between specific probes and specific abnormalities. In order to define the origin of supernumerary marker chromosome (SMC), Giardino et al used specific probes for FISH analysis. The researchers showed that the marker was specific for WCP2 and D2Z probes, (see figure 1b). Giardino et al conclude that FISH analysis using unique sequences are useful means of obtaining information about the euchromatic regions contained in an SMC and delineating new chromosomal syndromes. However, Giardino et al do not disclose that the claimed nucleic acid was one of the probes they used, neither do they establish a link between the claimed nucleic acid and any condition or disorder. Similarly, all of the other references submitted by Applicants as Exhibits 2-6, disclose either duplication, triplication, or proximal trisomy associated with chromosome 2q11.2.

Although the use of the claimed nucleic acid in a research setting to detect abnormalities or the presence of specific polymorphism is not dispositive of a lack of "real world" utility, however, the instant specification does not disclose any abnormalities or disorders that can be diagnosed using the claimed nucleic acid. The biological or physiological significance of the claimed nucleic acid, as a diagnostic tool has not been established by Applicants. For example, if a novel nucleic acid is shown to be expressed in colon cancer and not expressed in healthy colon tissue, but there is no disclosure of the biological activity of the polypeptide encoded by the nucleic acid, said

Art Unit: 1647

nucleic acid would not be rejected under 35 U.S.C. §§ 101 and 112, first paragraph, as it has utility and is enabled as a colon cancer marker. However, such is not the fact pattern in the instant case.

Therefore, the claimed nucleic acid lacks substantial utility, because Applicants have not taught which abnormalities that map to chromosome 2 can the claimed nucleic acid be used to identify. Furthermore, the polymorphisms identified for the nucleic acid of SEQ ID NO:3, are not associated with a specific condition, as a result, one of ordinary skill in the art would be able to predict which conditions that might be associated with these polymorphisms.

3b. Claims 1, 11, 15, 17 and new claims 32-38 stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record set forth in the action mailed on 21 August 2002 in Paper NO:7, pages 6-9 and reiterated on the office action mailed on 03 June 2003, pages 3-7.

Specifically, the fact that claimed nucleic acid maps on human chromosome 2, 2q11-12, does not provide specific or substantial utility for the claimed nucleic acid, because there is no information regarding the association of the claimed nucleic acid and any disease. Thus, one of ordinary skill in the art would not know how to use the claimed nucleic acid. Furthermore, since the polymorphisms identified for the nucleic acid of SEQ ID NO:3, are not associated with a specific condition, one of ordinary skill in the art would be able to predict which conditions that might be associated with these polymorphisms and therefore, would know how to use said polymorphism, to identify subjects that might be susceptible for a certain disorder.

Conclusion:

4. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wednesday-Thursday, 6:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4227.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647

Application/Control Number: 09/769,878
Art Unit: 1647

Page 7

04 December 2004


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600